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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,995	08/10/2001	Joe Reyes	3124.00015	7386

7590 03/26/2003

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,995

Applicant(s)

REYES, JOE

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application claims priority to provisional application Serial No. 60/230,656.

Election/Restrictions

Applicant's election with traverse of the invention of Group II, Claims 10-18, in Paper No. 5, submitted January 3, 2003 is acknowledged. The traversal is on the ground(s) that Group I and II should be combined as they are both classified in class 514/177 for example. Applicant also asserts that the purpose of Group I and II is identical, but Applicant admits that Group I and II are used for the opposite sex and there are only minor difference.

Applicant's traverse is not found persuasive. As discussed in the Restriction Requirement, Group I and II are unrelated to each other. The composition in claim 1 (Group I) requires a compound to increase blood flow to the pelvic area, whereas the composition in claim 10 (Group II) requires a compound for driving blood flow to the penis. Thus, the major ingredient in two compositions of Group I and II are different and distinct since one of ordinary skill in the art would clearly recognize that there are well known anatomical differences between female and male genitalia. Moreover, the biochemical basis, i.e., involvement of hormonal components for male sexual function vs. female sexual function are well known to be distinctive and independent. Therefore, since Group I and II are drawn to two separate and distinct compositions. Group I and II have different modes of operation.

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Therefore, the search for the inventions of both Groups I and II would place an undue burden on the Office. Note regarding the classification of the inventions herein that the search is not limited to the patent files.

Therefore, the requirement is still deemed proper and is made FINAL.

Claims 1-9 and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 10-18 will be examined on the merits herein.

Claim Objection

Claim 11 is objected to for minor informalities. According to MPEP 608.01(m) "Each claim begins with a capital letter and ends with a period". A period is missing in this claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular compound for driving blood flow to the penis, the particular aphrodisiac, the particular testosterone production compound for increasing natural production of testosterone, the particular

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heightening compound which heightens sexual arousal, function and performance disclosed in the specification (see page 12 of the specification herein) in composition herein, does not reasonably provide enablement for the employment any compounds for driving blood flow to the penis, any aphrodisiacs, the particular testosterone production compounds for increasing natural production of testosterone, any heightening compounds which heightens sexual arousal, function and performance recited in the claims herein.

These recitations, “a compound for driving blood flow to the penis”, “an aphrodisiac”, a “testosterone production compound for increasing natural production of testosterone”, and a “heightening compound which heightens sexual arousal, function and performance” and other similar recitations in claims 14-18, are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

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The nature of the invention: The instant invention pertains to a composition for boosting the libido of an individual.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claim 10) reads on any compounds for driving blood flow to the penis and any aphrodisiacs employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does “little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”. The CAFC further clearly states that “[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus..” at 1406 (emphasis added).

In the instant case, “a compound for driving blood flow to the penis”, “an aphrodisiac”, a “testosterone production compound for increasing natural production of

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testosterone”, and a “heightening compound which heightens sexual arousal, function and performance” and other similar phrases in claims 14-18, recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides one particular compound for each kind of functional compounds for the composition in claims 10-18 (the elected invention) (see page 12 of the specification).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor “inform the public during the life of the patent of the limited of monopoly asserted” (*General Electric Company v. Wabash Appliance Corporation et al. supra*, at 468).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of

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fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a male) the **combination** of any compounds represented by “a compound for driving blood flow to the penis”, “an aphrodisiac”, a “testosterone production compound for increasing natural production of testosterone”, and a “heightening compound which heightens sexual arousal, function and performance”, which may encompass more than a thousand compounds. See text book “Goodman & Gilman’s The Pharmacological Basis of Therapeutics” regarding possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that “The frequency of significant beneficial or adverse drug interactions is unknown” (see the bottom of the left column of page 51) and that “Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed” and that “The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences” (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible adverse drug-drug interactions occurring with many combinations

of any compounds having claimed functional properties in the pharmaceutical compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only one particular compound for each kind of functional compounds employed in the composition herein is disclosed in the specification. Moreover, it is noted that the specification fails to provide working examples, i.e., testing results or data to demonstrate the instant compositions (different combinations of the claimed compounds) to be administered to a host, i.e., a male, in treating for boosting the libido and/or treating sexual dysfunction in a male.

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice

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the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "natural" in claim 10 renders claims 10-18 indefinite. The term "natural" is not defined in the specification. It is unclear as to the meaning of the term "natural" in the claims herein. The term "natural" could be interpreted according to its ordinary and customary meaning provided by a dictionary:

Natural: "Present in or produced by nature" and/or "Not treated, altered, or disguised" (see Webster's II New Riverside University Dictionary 1994, PTO-892).

Applicant is requested to note that products of nature are not patentable subject matter under 35 U.S.C. 101.

The expression "the circulation of smooth blood flow" in claim 14 renders claim 14 indefinite. This expression is not defined in the specification. Hence, one of ordinary skill in the art could not interpret as to the recitation " smooth blood flow " in the claim. It

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is noted that the instant specification describes "smooth muscles" (see page 9 the first paragraph).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese herbal composition "dzan yu dan" (A Handbook of Chinese Healing Herbs, page 243-244, PTO-892).

The particular Chinese herbal composition, "dzan yu dan", for treating impotence and/or infertility including erectile dysfunction in man comprising compounds for driving blood flow to the penis and aphrodisiacs and compounds known to inherently have functions recited in the instant claims including enhancing sexual performance, with a pharmaceutical acceptable carrier (i.e., water) in an orally administrable form (see page 243-244, in particular the ingredients at page 244).

Thus, this herbal composition, "dzan yu dan" anticipates the claimed invention.

Claims 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese herbal composition "wu dze tang" (A Handbook of Chinese Healing Herbs, page 244-245, PTO-892).

The particular Chinese herbal composition, "wu dze tang" for treating impotence and/or infertility in man including erectile dysfunction and low sperm count comprising compounds for driving blood flow to the penis and aphrodisiacs and compounds known to inherently have functions recited in the instant claims including enhancing sexual performance, with a pharmaceutical acceptable carrier (i.e., water) in an orally administrable form (see page 244-245, in particular the ingredients at page 244-245).

Thus, this herbal composition, "wu dze tang" anticipates the claimed invention.

Claims 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese herbal composition "mi jing tang" (A Handbook of Chinese Healing Herbs, page 246-247, PTO-892).

The particular Chinese herbal composition, "wu dze tang" for treating impotence and/or infertility in man including erectile dysfunction and involuntary loss of semen and related symptoms comprising compounds for driving blood flow to the penis and aphrodisiacs and compounds known to inherently have functions recited in the instant claims including enhancing sexual performance, with a pharmaceutical acceptable carrier in an orally administrable form (see 246-247, in particular the ingredients at page 246).

Thus, this herbal composition, "mi jing tang" anticipates the claimed invention.

Moreover, it is noted that it has been held that "Some prior dicta exist which would seem to support the proposition that a claim broadly reciting a naturally occurring

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chemical compound may be rejected as unpatentable over a naturally occurring composition containing that compound even though the compound's existence is not known". For instance, in *In re Bergstrom*, 57 CCPA 1240, 427 F.2d 1394, 166 USPQ 256 (1970).

In view of the rejection to the pending claim set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
March 21, 2003